IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BENTLEY A. HOLLANDER,	:	CIVIL ACTION
	:	
Plaintiff,	:	
	:	
v.	:	NO. 10-00836
	:	
ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.	:	
	:	
Defendant.	:	

MEMORANDUM

BUCKWALTER, S. J. April 4, 2011

Presently before the Court is the Motion of Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho") to Dismiss the Amended Complaint of Plaintiff Bentley A. Hollander pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the Court denies the Motion to Dismiss.

I. FACTUAL AND PROCEDURAL BACKGROUND

On March 1, 2010, Plaintiff/Relator Bentley A. Hollander, a resident of Philadelphia, Pennsylvania, commenced this *qui tam* action on behalf of the United States against Defendant Ortho, a pharmaceutical company headquartered in New Jersey, for violations of the federal false marking statute, 35 U.S.C. § 292(a). According to the facts set forth in the Amended Complaint, Defendant Ortho is a sophisticated global healthcare products business with annual sales of hundreds of millions of dollars. (Am. Compl. ¶¶ 9, 11.) The company manufactures and sells products throughout the United States and "claims to own or have licenses under a substantial

number of patents issued and pending." (Id. ¶¶ 10, 13.)

Plaintiff alleges that Defendant Ortho has injured the sovereign interests of the United States and discouraged competition by "repeatedly and knowingly" marking units of its prescription drug products with expired patents.[1] (Id. ¶ 2.) Plaintiff further asserts that Defendant has engaged in such false marking with "the purpose of deceiving the public into believing that the products were covered by valid patents when, in fact, such patents had expired." (Id.) Based on these allegations, Plaintiff brings forty-one counts of false marking against Defendant (id. ¶¶ 105-350) and seeks up to a $500 fine per violation, one half of which is to be paid to the United States pursuant 25 U.S.C. § 292(b). (Id. at Prayer for Relief.)

On May 18, 2010, Defendant moved to stay the case pending resolution of two cases in the Federal Circuit, or in the alternative, to dismiss based on Plaintiff's insufficient standing and failure to state a claim. On October 21, 2010, this Court denied the Motion to Stay and granted the Motion to Dismiss without prejudice, finding that Plaintiff had standing to bring the claim but had failed to state a claim upon which relief could be granted. Hollander v. Ortho-McNeil-Janssen Pharms., Inc., No. CIV.A.10-00836, 2010 WL 4159256 (E.D. Pa. Oct. 21, 2010).

Plaintiff filed an Amended Complaint on November 22, 2010. On December 9, 2010, Defendant moved to dismiss the Amended Complaint for failure to state a claim. Plaintiff filed a Response in Opposition on December 30, 2010, and Defendant filed a Reply on January 10, 2011. Plaintiff filed a Sur-Reply on January 18, 2011, and Defendant filed a Notice of

[1] These products include varying forms and dosages of Risperdone, allegedly marked with U.S. Patent No. 4,804,663 (expiration: Dec. 29, 2007); Nizoral, No. 4,335,125 (exp. June 15, 2000); Terconazole, No. D279,504 (exp. Jul. 2, 1999); Ofloxacin, No. 4,382,892 (exp. Sept. 2, 2003); and Razadyne, No. 4,663,318 (exp. Dec. 14, 2008).

Supplemental Authority on March 21, 2011. The Court now considers Defendant's Motion.

II. DISCUSSION

To state a false marking claim under § 292, a plaintiff must show "(1) a marking importing that the article is patented (2) falsely affixed to (3) an unpatented article (4) with the intent to deceive the public." Brinkmeier v. Graco Children's Prods., 684 F. Supp. 2d 548, 551 (D. Del. 2010) (citing Clontech Labs., Inc. v. Invitrogen Corp., 406 F.3d 1347, 1352 (Fed. Cir. 2005); Juniper Networks v. Shipley, No. CIV.A.09-0696, 2009 WL 1381873, at *3 (N.D. Cal. May 14, 2009)). Plaintiff avers that Defendant has intentionally marked the aforementioned prescription drug products with patent numbers Defendant knew to be expired. He further alleges that Defendant has done so "for the purpose of deceiving the public in order to achieve commercial gain, to enable false advertising, to quell competition, and to deceive generic drug manufacturers into thinking that the drug continues to be covered by a patent in order to decrease competition." (Am. Compl. ¶ 8.) Defendant moves to dismiss the Amended Complaint for failure to sufficiently allege the deceptive intent element of § 292.

A. Standard of Review

Under Rule 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. FED. R. CIV. P. 12(b)(6); see also Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005). Federal Rule of Civil Procedure 8 does not call for detailed factual allegations; rather, it requires a short and plain statement of the claim showing that the pleader is entitled to relief. FED. R. CIV. P. 8; Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). Further, the court must "accept all factual allegations in the complaint as true and view them in the light most favorable to the plaintiff." Buck v. Hampton

Twp. Sch. Dist., 452 F.3d 256, 260 (3d Cir. 2006).

The Supreme Court has made clear, however, that "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Instead, the plaintiff must offer "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570. To do so, the plaintiff must show "more than a sheer possibility that a defendant has acted unlawfully." Ashcroft, 129 S. Ct. at 1949 (citing Twombly, 550 U.S. at 556-57); see also Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009) (adopting Iqbal's standards).

In the recent case of In re BP Lubricants USA Inc., No. CIV.A.960, 2011 WL 873147 (Fed. Cir. Mar. 15, 2011), the Federal Circuit ruled that § 292's required showing of deceptive intent invokes the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). Id.; accord Hollander v. Etymotic Research, Inc., 726 F. Supp. 2d 543, 551 (E.D. Pa. July 14, 2010); Brinkmeier v. BIC Corp., 733 F. Supp. 2d 552, 563 (D. Del. 2010). "Rule 9(b) may be satisfied by describing the circumstances of the alleged fraud with precise allegations of date, time, or place, or by using some means of injecting precision and some measure of substantiation into the allegations of fraud." Hollander v. Ranbaxy Labs. Inc., No. CIV.A.10-793, 2011 WL 248449, at *3 (E.D. Pa. Jan. 24, 2011) (citing Bd. of Trs. of Teamsters Local 863 Pension Fund v. Foodtown, Inc., 296 F.3d 164, 172 n.10 (3d Cir. 2002)). "Stated another way, the plaintiff must plead the who, what, when, where, and how of the fraud." Id. (citing Institutional Investors Grp. v. Avava, Inc., 564 F.3d 242, 253 (3d Cir. 2009); Bonavitacola Elec. Constr. v. Boro Developers, Inc., No. CIV.A.01-5508, 2003 WL 329145, at *6 (E.D. Pa. Feb. 12, 2003)).

In the context of false marking claims, courts have noted that "a relaxed Rule 9(b) standard may apply when 'essential information lies uniquely within another party's control.'" BIC, 733 F. Supp. 2d at 559 (quoting Exergen v. Wal-mart Stores, Inc., 575 F.3d 1312, 1330-31 (Fed. Cir. 2009); In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997)). As a result, "a plaintiff may plead based upon information and belief, 'but only if the pleading sets forth specific facts upon which the belief is reasonably based.'" Id. "[B]oilerplate and conclusory allegations will not suffice." BIC, 733 F. Supp. 2d at 559 (citing Burlington, 114 F.3d at 1418). Instead, plaintiffs must offer "factual allegations that make their theoretically viable claim plausible." Id.

With regard to the deceptive intent prong of § 292, the Federal Circuit has held that "the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent." BP Lubricants, 2011 WL 873147, at *3 (quoting Clontech, 406 F.3d at 1352). Thus, while "'knowledge' and 'intent' may be averred generally," Federal Circuit precedent "requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." Id. (quoting Exergen, 575 F.3d at 1327).

B. Whether Plaintiff has Sufficiently Alleged Deceptive Intent

Defendant first contends that its compliance with the Hatch-Waxman Act, 21 U.S.C. § 355, precludes Plaintiff from setting forth plausible allegations that Defendant intended to deceive the public. The Hatch-Waxman Act requires pharmaceutical companies to file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA") in order to obtain approval to manufacture and sell new drugs. (Def.'s Mot. Dismiss 6 (citing 21 U.S.C. § 355(a)).)

According to Defendant, these NDAs require companies to list the number and expiration date of each patent covering a new product. (Id.) This information is then listed in the Orange Book, an official FDA publication available to the public online. (Id.) Given the accessibility of patent information online, Defendant reasons that its compliance with the Act means Plaintiff cannot plausibly allege that Defendant has "deceived" the marketplace.[2] (Id.)

The Court disagrees, finding that the Federal Circuit's ruling in Clontech, 406 F.3d at 1356-57, severely undercuts Defendant's theory. There, the Court stated that "Congress intended the public to rely on marking as 'a ready means of discerning the status of intellectual property embodied in an article of manufacture or design.'" Id. at 1356 (quoting Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 162 (1989)). The court went on to reason that false marking harmed the public's interest in free competition because it "externalizes the risk of error in the determination [of whether a patentee controls the article in question], placing it on the public rather than the manufacturer or seller of the article, and increases the cost to the public of ascertaining whether a patentee in fact controls the intellectual property embodied in an article." Id. Similarly, in Forest Group, Inc. v. Bon Tool Co., 590 F.3d 1295, 1303 (Fed. Cir. 2009), the court stated that "false marking can also cause unnecessary investment in design around or costs incurred to analyze the validity or enforceability of a patent whose number has been marked upon a product with which a competitor would like to compete." Id.; see also San Francisco Tech., Inc. v. Sunstar Ams., Inc., No. CIV.A.10-5000, 2011 WL 291168, at *5 (N.D. Ill. Jan. 27, 2011) (rejecting Defendant's argument that an expired patent could not deceive members of the

[2] Plaintiff sets forth no allegations of Defendant's non-compliance with the Act in his Amended Complaint, but does not concede that Defendant did so comply. (Pl.'s Resp. Opp'n 5 n.1.)

public because patent's expiration date was available online, finding that false marking could still "dissuad[e] competition from potential entrants into the relevant market") (citing Bon Tool, 590 F.3d at 1303). Thus, Defendant's argument fails.

Defendant next argues that, prior to the Federal Circuit's ruling in Pequignot v. Solo Cup Co., 608 F.3d 1356 (Fed. Cir. 2010) in June of 2010, pharmaceutical companies had no explicitly-stated duty to remove expired patent markings from product packaging. (Def.'s Mot. Dismiss 11.)[3] As such, Defendant claims that its failure to remove the expired markings before June 2010 was in no way inconsistent with patent law at that time, and thus cannot suggest an intent to deceive. (Id.) As discussed above, however, Federal Circuit precedent allows the Court to infer deceptive intent based on specific allegations that the defendants knew a patent was expired at the time of marking. Whether Defendant did, in fact, have such an intent – versus mere negligent behavior – is a question of fact inappropriate for this stage of litigation.

More broadly, Defendant asserts that Plaintiff's allegations of deceptive intent are too conclusory to withstand the pleading requirements of Rule 9(b). The Court again disagrees. Plaintiff's initial Complaint alleged that Defendant knew the disputed patents were expired solely based on Defendant's status as a sophisticated business entity with patent experience. Hollander, 2010 WL 4159256, at *5. In contrast, the Amended Complaint asserts that Defendant had a working knowledge of the aforementioned patents due to (1) Defendant's active involvement in litigation over three of the patents, and (2) applications by generic drug manufacturers to the Center for Drug Evaluation and Research ("CDER") seeking to produce two of the drugs at issue

[3] Pequignot clarified that an article covered by a now-expired patent is "unpatented" for the purpose of false marking claims. 608 F.3d at 1361.

after their respective patents expired.

1. Risperdone (Counts I-XXV), Ofloxacin (Counts XXXII-XXXIV), and Razadyne (Counts XXXV-XLI)

With respect to Plaintiff's Risperdone claims (Counts I-XXV, patent no. '663), Plaintiff alleges that Defendant sought an injunction in 2006 to stop two generic drug manufacturers from producing the drug. (Am. Compl. ¶ 33.) The District Court of New Jersey purportedly granted the injunction, stating that it would remain effective until the expiration of the patent on December 29, 2007. (Id.) Notwithstanding this knowledge, Plaintiff asserts that Defendant published new packaging marked with the expired number on January 1, 2008, October 2, 2009, February 26, 2010, April 16, 2010, and October 21, 2010. (Id. ¶¶ 35-37.)

Similarly, Plaintiff avers that Defendant knew of the expiration of its Ofloxacin patent (Counts XXXII-XXXIV, patent no. '892) based on its 2003 suit in the Northern District of West Virginia against a generic drug manufacturer for infringement of the patent. (Id. ¶ 81.) According to Plaintiff, Defendant was specifically put on notice of the patent's expiration by the court's 2004 opinion, which stated that the patent had expired on August 2, 2003. (Id. ¶¶ 81-82.) Defendant has purportedly published new Ofloxacin packaging using the expired patent number at least twice since the issuance of the opinion, on May 22, 2007 and January 1, 2008. (Id. ¶ 84.)

With regard to Counts XXXV-XLI (Razadyne, patent no. '318), Plaintiff alleges that Defendant was actively involved in litigation over the Razadyne patent the same year as its expiration (December 14, 2008). (Id. ¶¶ 94, 96.) Moreover, Plaintiff avers that the court in that case ultimately found the patent invalid due to lack of enablement. (Id. ¶ 96.) Notwithstanding this purported knowledge, Defendant has allegedly continued to mark its products with the

expired '318 patent. (Id. ¶¶ 99-100.)

Both the Federal Circuit and courts within the Third Circuit have noted that intent to deceive may be inferred from a defendant's active involvement in litigation over a disputed patent. See, e.g., BP Lubricants, 2011 WL 873147, at *4 (noting with approval United States' suggestion, in amicus brief, that a relator might set forth sufficient underlying facts from which a court could infer intent to deceive by "alleg[ing] that the defendant sued a third party for infringement of the patent after the patent expired"); Graco, 684 F. Supp. 2d at 553 (finding infringement suit against defendant by two competitors and at least three revisions of markings since patent's expiration sufficient to allege deceptive intent); BIC, 733 F. Supp. 2d at 564 (citing defendant's involvement in litigation as one way to "imply a working knowledge of the patents, conscious knowledge of the scope and expiration date"). The Court thus finds these allegations sufficient to support an inference of deceptive intent.

2. Nizoral (Counts XXVI-XXVIII) and Terconazole (Counts XXIX-XXXI)

In support of Counts XXVI - XXVIII (Nizoral, patent no. '125), Plaintiff avers that Defendant was put on notice of the Nizoral patent's expiration by applications of at least two generic drug companies to the CDER to make and sell a generic version of the drug after the patent's expiration. (Am. Compl. ¶ 49.) According to Plaintiff, these applications explicitly listed the patent's June 15, 1999 expiration date. (Id.) Plaintiff then identifies three specific Nizoral products for which Defendant has published new packaging since the date of the patent's expiration, on February 16, 2007, September 18, 2008, September 4, 2009, and May 10, 2010. (Id. ¶ 52.)

Similarly, in reference to Counts XXIX-XXXI (Terconazole, patent no. '504), Plaintiff alleges that Defendant has knowingly published new packaging four times since the expiration of its patent, on April 26, 2007, April 18, 2008, December 16, 2009, and June 1, 2010. (Id. ¶ 68.) Plaintiff again claims that Defendant knew of the patent's expiration as a result of an application filed by Taro Pharmaceuticals to the CDER to make and sell the drug after the patent's July 2, 1999 expiration. (Id. ¶ 65.) This application was subsequently approved on January 19, 2005. (Id.)

Current jurisprudence suggests that allegations of only a single, unspecified instance of package revision with an expired marking is not, by itself, sufficient to support an inference of deceptive intent. See, e.g., BIC, 733 F. Supp. 2d at 563-65 (finding insufficient plaintiff's allegations that defendant knew patents had expired merely because it updated product packaging following patent expiration); Shizzle Pop, LLC v. Wham-O, Inc., No. CIV.A.10-3491, 2010 WL 3063066, at *4 (C.D. Cal. Aug. 2, 2010) ("[C]reating new packaging does not create a reasonable inference that Defendant knew the '678 patent had expired.") At the same time, courts have been receptive to plaintiffs alleging *multiple* packaging revisions, particularly where such allegations are detailed or coupled with other indicia of the defendant's knowledge of a patent's expiration. See, e.g., Graco, 684 F. Supp. 2d at 553 (denying motion to dismiss where plaintiff alleged multiple revisions in addition to defendant's involvement in infringement litigation concerning the patents at issue); BP Lubricants, 2011 WL 873147, at *4 (noting "that a relator can, for example, allege that the defendant sued a third party for infringement of the patent after the patent expired *or* made multiple revisions of the marking after expiration") (emphasis added); BIC, 733 F. Supp. 2d at 563-64 (citing Graco with approval, but finding plaintiff's allegations of

packaging revisions insufficient where he failed to specify when and which products were mismarked or offer further allegations indicating "conscious knowledge of the scope and expiration date").

In the instant case, Plaintiff has identified multiple instances of post-expiration packaging revision (including the dates on which these alleged revisions occurred). Plaintiff further alleges that Defendant was put on notice of the expiration of the Nizoral and Terconazole patents via the aforementioned CDER applications. Taken as true, these allegations go beyond the mere conclusory assertions of Plaintiff's original Complaint, and are sufficient to withstand Defendant's Motion to Dismiss.

III. CONCLUSION

In light of the foregoing, the Court finds Plaintiff has set forth a sufficient factual basis from which the Court may infer an intent to deceive drug manufacturers and the public at large. Plaintiff has thus fulfilled the heightened pleading standards of Rule 9(b). Accordingly, Defendant's Motion is denied.

An appropriate Order follows.